REMARKS

The above amendments and these remarks are submitted in response to the Office Action of May 21, 2003. In the Office Action, which was made final, the Examiner rejected claims 22, 23, 40 and 46 under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,459,917 (Gowda et al.). Claims 24-39, 41,45 and 47-55 were rejected under U.S.C. § 103(a) as being unpatentable over the Gowda et al. patent, in view of U.S. Patents 5,441,481 (Mishra et al.) and 5,607,390 (Patsalos et al.). Each of these rejections is traversed in view of the following remarks, and Applicant submits that the claims are patentable over the prior art of record. Accordingly, and in view of the accompanying Request for Continued Examination, reconsideration and a Notice of Allowance are requested.

Rejection under 35 U.S.C. § 102

Claims 22, 23, 40 and 46 were rejected under 35 U.S.C. § 102(e) as being anticipated by Gowda et al. These rejections are traversed.

As reflected on the application data sheet of the present application, and the Preliminary Amendment filed August 23, 2001, the present application is a continuation of a U.S. non-provisional application, Ser. No. 09/314,919, filed May 19, 1999, which claims priority to German application 198 22 711.6, filed May 20, 1998.

The Gowda et al. patent cited by the Examiner issued October 1, 2002, and was filed May 22, 2000. Thus, by date alone, Gowda et al. cannot be a prior art reference to the present application. A certified copy of the German priority application has been filed in the U.S. parent application (Ser. No. 09/314,919). Further, pursuant to 37 CFR 1.55(a)(4), Applicant has enclosed herewith an accurate translation of the priority document. The Examiner's attention is respectfully directed to 37 CFR 1.55(a)(4) and to the MPEP, Chapter 706.02(b)(E) and (F).

Although it cannot be the basis for a rejection by reason of date alone, applicant further notes that the Gowda et al. patent does not disclose or suggest a tube arrangement extending into the body as recited in the independent claims.

For at least these reasons, the § 102 rejection based on the Gowda et al. patent cannot be maintained.

Rejection under 35 U.S.C. § 103

Claims 24-39, 41-45, and 47-55 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Gowda et al., in view of Mishra et al. and Patsalos et al. These rejections are traversed.

Just as the § 102(e) rejection based on Gowda et al. cannot stand for at least the reasons stated above, similarly the § 103 rejection which is based on Gowda et al. as a primary reference cannot be maintained. The Mishra et al. patent and Patsalos et al. references cited by the Examiner simply do not disclose a method for analyzing body fluids by implantable means comprising a port body and tube arrangement implanted in a patient's body as recited in the independent claims of the present application. The dependent claims rejected under § 103 are patentable for at least the same reason.

Conclusion

Notwithstanding the above remarks, claim 23 has been cancelled without disclaimer and the dependencies in the dependent claims have been amended accordingly.

The above amendments do not generate any additional claim fees. However a Petition to extend the time to respond by three months from August 21, 2003 until November 21, 2003 is enclosed herewith, along with the Request for Continued Examination. Checks in the amount of $770.00 and $950.00 are enclosed to cover the fees associated with the Petition and the Request. The Office is also hereby authorized to charge any additional fees associated with this communication, the Request or Petition to Deposit Account 04-1420.

The application is in allowable condition, and reconsideration and a formal Notice of Allowance are respectfully requested.

The Examiner is invited to telephone the undersigned if doing so will help advance the application.

Respectfully submitted,

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Attorney's File No. 43 366 XI

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Sensor system including a port body

The invention refers to a process and a device for detecting the concentration and/or existence of substances in body fluids and the use of an access means to the interior of the body, implanted in the body, for the purpose of the said detection.

A number of procedures exist in medicine for detecting the concentration and/or existence of substances in body fluids. When testing for blood sugar concentration, for instance, there is the option on the one hand of piercing the patient's skin, such as on a finger, for testing the blood sugar content of any blood drawn in this manner and/or any intercellular fluid by a test strip. Furthermore, the option of piercing thin needles for retraction or introducing a sensor at a test point into the body is being used.

However, these invasive techniques are always lumbered with the drawback that they are unpleasant experiences to the patient. In addition, needle-type sensors will fail due to being affected and/or rejected by the body after a very short time (approximately half a day).

Non-invasive techniques, such as for instance detecting said concentration by fluoroscopic methods have not been adequately developed yet in order to obtain sufficiently accurate values. Port bodies, implanted subcutanously or percutanously and

used for administering drugs through tubular channels, are, for instance, known from US-A-5,306,255 and EP-B-0 302 076.

It is the object of this invention to provide a method and a device for detecting the concentration and/or existence of substances in body fluids by which the disadvantages of the state of technology described above are overcome in as far as possible, in particular to avoid inconvenience to patients.

The inventive method for detecting the concentration and/or existence of substances in body fluids attains this object by accessing the interior of the body and any fluids to be analysed by an access means implanted permanently in the body.

Many patients needing regular medication due to the concentrations of certain substances in their body fluids being too low or too high, are being administered said medication by artificial access means to the interior of their body. The process according to the invention now has the target of using access means permanently implated in the body for gaining access to the said body fluids. Said access means, permanently implanted in the body, which may comprise quick-replacement elements, such as a framed sealing diaphragm, mostly end at parts of the body where no blockage of their endings will occur for some length of time or are designed to ensure that attacks by or rejection mechanisms of body cells will not affect their function at least over a predetermined period of use. According to the invention, this benefit may now also be used for access to body fluids by the said access means. This means that the said permanent access means allows access to the said fluids for analysis over an extended period of time.

Access is therefore preferably effected through a permanently implanted device for administering medicaments and, in a said especially preferred embodiment of the process according to the invention, through a port body implanted in the skin, comprising a tubular arrangement extending into the interior of the body.

In particular, the port body is suitable as a permanent means of access for administering insulin, preferably implanted into the umbilical vein within the abdominal cavity of the body.

The abdominal cavity, the peritoneum and the umbilical vein have proven to be advantageous sites for the administration of insulin, due to insulin being resorbed faster there than after subcutaneous administration, for instance. Owing to the fact that insulin consumption takes place in the body cells as such, the cell fluid also seems a very suitable place to measure the blood sugar content, due to measuring a central average in this case directly at the place of consumption. Accordingly, port bodies for the administration of insulin into the abdominal cavity and as access points according to the invention to the body fluid to be analysed are very suitable.

Although said port bodies are invasive devices, one-time implantation will be sufficient, whereby the patient no longer experiences any inconvenience during subsequent access to body fluids through said port bodies.

One embodiment of the process according to the invention is characterized by a test sensor being introduced into the interior of the body through the access means for detecting the concentration and/or existence of substances, with detection being performed at that point. This opens a chance for continuous and intermittent testing, whereby the sensor remains at the test site in the interior of the body and is introduced via a separate tube when using a port body comprising a tubular system.

Another option for detection according to the invention by a test sensor remaining in the interior of the body is to take body fluid from the interior of the body through the access means, followed by analysis at a point remote from the point of retraction. Body fluid is still analysed, for instance, within the body, preferably at an intermediate point of the tubular system, by means of a sensor and is aspired for this purpose to this point. The benefit of using the said intermediate point as a test site can in particular be seen in the

fact that any deposits, which might arise at the end of the tube, by which access is effected, could not have any negative influence on the accuracy of tests in that case upon the test sensor being placed at an intermediate point remote from the end of the tube. Consequently, the tubular section located further towards the interior protects a test sensor, permanently provided at an intermediate point of the tube, against direct contamination. Furthermore, constancy of temperature is ensured. When the sensor is replaced, the abdominal cavity is not affected.

According to an alternative embodiment of the process according to the invention, body fluids may naturally be aspired away from the body for analysis.

In addition, a preferred embodiment of the invention uses a dialysis microprobe by which substances are retracted from body fluids.

The device for detecting the concentration and/or existence of substances in body fluids according to the invention comprises an access means to the interior of the body, permanently implanted in the body, adapted for allowing access to fluids for analysis through said access means.

Preferably the access means is a permanently implanted device for administering medicaments, in particular a port body implanted into the skin, comprising a tubular system extending into the interior of the body.

The access means for the device according to the invention and/or the port body preferably comprise passages by means of which a test sensor is introduced into the interior of the body. The said means of access and/or the port body preferably comprise a separate tube for the introduction of the said sensor.

An especially preferred design of the device according to the invention is characterized in that the access means is associated with a dialysis microprobe through which substances in body fluids are withdrawn.

Furthermore, the invention refers to the use of an access means to the interior of the body, permanently implanted in the body, through which the concentration and/or existence of substances in body fluids are detected. For said application, any of the advantageous embodiments of the process according to the invention and the device described above may be realised.

The invention will, in the following, be explained in detail by means of the enclosed figure, which is a diagram of an implanted port body adapted according to the invention.

Said port body, as a whole marked 10 the figure, is shown in a condition in which it has been implanted in the skin 15, comprising a shaft section 11 to which an approximately disc-shaped anchoring section 13 is attached, acting as an attachment for the port body 10 into the skin.

The shaft section 11 forms a hollow enclosure supporting an elastic self-closing diaphragm 12.

Separate tubes extend at the lower end from the port body 3, i.e. a feed tube 23, not shown over its full length in the figure, and a shorter aspiration tube 21. One catheter each may be introduced through the diaphragm 12 into each of the tubes 23 and 21, i.e. a feed catheter 24 and an aspiration catheter 22.

A point at the mouth of the tube 23 is supplied with a drug, such as insulin, through the feed catheter 24, whilst from a point at the end at the mouth of the tube 21 body fluids may be withdrawn through the aspiration catheter 22.

The diagram shows fastening sections 14 at the top of the shaft 11, provided for connection of the upper sealing and/or closing caps the catheters 24 and 22, not shown in the figure.

The feed tube is preferably of a standard length of 150 or 180 mm, whilst the aspiration tube 21 presumably has an approximate minimum length of 30 mm, preferably 60 to 120 mm, possibly even 180 mm. This arrangement therefore clearly shows that this port body may be used both for the supply of drugs through the feed catheter 24 and for access to body fluids through the aspiration catheter 22. The tubes 23 and 21 preferably extend into the patient's abdominal cavity where cell fluid can be found, which must either be provided with a drug or which is to be analysed for specific concentrations.

The dashed arrows show the various test sites for testing the concentration or existence of certain substances. In this case, a sensor has been applied to test point 25 where fluid is aspired from the bottom end of the catheter 22 somewhat upwards, in order to perform a test precisely at this intermediate point 25. As described above, the sensor attached here permanently to point 25 is protected against deposits by the lower section of the tube 21 and/or the catheter 22.

When a test is performed at a point where no major deposits are to be suspected, the test sensor may also be permanently attached at a point marked by the dashed arrow 26. The benefit of this detection method lies in the fact that aspiration is no longer required and detection will be feasible directly at the specified test point.

In the two embodiments described, where the test sensor remains permanently in the tube 25 and/or on the end of the tube 26, an electronic test sensor is used, the connecting wires of which may be taken out of the body together with the catheter 22.

At this point it is worth noting that most of the said electronic test sensors comprise a working electrode, a counterelectrode and a zero-current reference electrode. When the

shaft 11 of the port body (as this will be normally the case) is of a metallic material, the shaft 11, too, may according to the invention be used as a reference electrode or counterelectrode, thus allowing simplification of the electric sensor during the said tests according to the invention.

Another option for using the arrangement shown in the figure consists of only inserting one probe through the tube 21 for one-time testing or for each individual test, with its front end comprising a test strip for detecting the concentration. Taking and evaluation of a reading may be performed in inserted condition or after removal, based on a prior art procedure.

Finally, there is a very simple type of detection according to the invention by simply aspiring fluid from the interior of the body externally, away from the test site, through the catheter 22, as shown by the dashed arrow 27. Any body fluid obtained in this way may then be analysed in a laboratory in the familiar way.

Attorney's File No. 43 366 XI

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Sensor system including a port body

Claims

1. A method for detecting the concentration and/or existence of substances in body fluids, in which an existing fluid is accessed for analysing the said fluids via an access means permanently implanted in the body.

2. A method as set forth in claim 1, characterized in that access is provided via a permanently implanted device for administering medicaments.

3. A method as set forth in claim 1 or 2, characterized in that access is provided via a port body (10) implanted in the skin, including a tube arrangement (20) extending into the interior of the body and being implanted in the body, preferably in the abdominal area or in the umbilical vein, as a permanent access means, in particular for administering insulin.

4. A method as set forth in one of the claims 1 to 3, characterized in that a test sensor

is inserted into the interior of the body via said access means for detecting the concentration and/or existence of substances for carrying out the detection in that location.

5. A method as set forth in claim 4, characterized in that said test sensor remains at the test site in the interior of the body for continuous testing, said test sensor in particular being inserted via a separate tube (21).

6. A method as set forth in one of the claims 1 to 5, characterized in that body fluid is withdrawn from the interior of the body via said access means and analysed at a location distanced from the point of withdrawal.

7. A method as set forth in claim 6, characterized in that the body fluid is analysed by means of a sensor while still in the body, preferably at an intermediate site (25) of said tube arrangement by means of said sensor and is aspirated towards this site.

8. A method as set forth in one of the claims 1 to 3, characterized in that body fluid is analysed outside the body.

9. A method as set forth in one of the claims 1 to 8, characterized in that the substances contained in the body fluid are withdrawn by means of a microdialysis probe associated with said access means.

10. A device for detecting the concentration and/or existence of substances in body fluids,

said device comprising an access means to the interior of the body, permanently implantable in the body, adapted for analysis of fluids to allow access via the said access means to the said fluids.

11. A device as set forth in claim 10, characterized in that said access means is a permanently implantable device for administering medicaments, in particular a port body (10), implantable in the skin and comprising a tube arrangement (20) extending into the interior of the body.

12. A device as set forth in claims 10 or 11, characterized in that said access means and/or said port body (10) comprise passages by means of which the test sensor may be guided into the interior of the body.

13. A device as set forth in claim 12, characterized in that said access means and/or said port body comprise a separate tube (21) for the insertion of a test sensor.

14. A device as set forth in one of the claims 10 to 13, characterized in that said access means is associated with a microdialysis probe via which substances in the body fluid may be withdrawn.

15. Use of an access means to the interior of the body, permanently installed in the body, for detecting the concentration and/or existence of substances in body fluids.

ABSTRACT OF THE DISCLOSURE

SENSOR SYSTEM INCLUDING A PORT BODY

The invention refers to the detection of the concentration and/or existence of constituents in body fluids, access being provided for analysing the fluids existing in the body via an access means to the interior of the body, permanently implanted in the body. In addition, the invention refers to a device for detecting the concentration and/or existence of constituents in body fluids as well as the use of an access means to the interior of the body, permanently implantable in the body for detecting the concentration and/or existence of constituents in body fluids.